"Apparatus and Method for Treating Female Urinary Incontinence"

The present invention relates to an apparatus and method for treating female urinary incontinence. In particular, the invention provides a surgical implant that passes under the urethra in use and supports the urethra, the implant being anchored in the retropubic space is provided.

Urinary incontinence affects a large number of women and, consequently, various approaches have been developed to treat female urinary incontinence. Those skilled in the art will be familiar with approaches ranging from pelvic floor exercises to surgical techniques such as Burch colposuspension and Stamey-type endoscopic procedures in which sutures are placed so as to elevate the bladder neck.

This invention is particularly directed to improvement of a known procedure in which a sling is

positioned loosely under the urethra, commonly known as TVT (tension free vaginal tape) and described, for example, in International Patent Applications No. WO97/13465 and WO96/06567. It is generally understood that this treatment alleviates urinary incontinence by occluding the mid-urethra (for example at a time of raised abdominal pressure by coughing or the like).

In order to provide a sling loosely under the urethra using the apparatus and method of the prior art, an incision is made in the anterior vaginal wall and a first needle is passed through the incision, past one side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower anterior abdominal wall. Likewise, a second needle is passed through the incision, past the other side of the urethra, behind the pubic bone, through the rectus sheath and out through the lower abdominal wall. The needles are separated from their respective insertion tools and also from the mesh or tape such that only the tape and its plastics sleeve are left in the body, passing from a first exit point in the lower abdominal wall, through the rectus sheath, behind the pubic bone, under the urethra, back behind the pubic bone, back through the rectus sheath and out through a second exit point in the lower abdominal wall.

The plastics sleeve is then removed from the tape and the tape adjusted to a suitable tension (such

that the tape provides a sling that passes loosely under the urethra, as described above) by manoeuvring the free ends of the tape outside the exit points in the lower abdominal wall whilst the urethra is held using a rigid catheter inserted therein. The tape is then cut such that it just falls short of protruding from the exit points in the lower abdominal wall. The exit points and the incision in the upper vaginal wall are then closed by sutures.

Whilst highly effective in treating urinary incontinence, this procedure has a number of problems. One such problem is that the needles used for inserting the tape are comparatively large, with the needles having, for example, a diameter of around 5-6 mm and a length of around 200 mm. As well as causing concern for patients viewing such needles before or in some cases during the procedure, the size of the needles can also lead to a high vascular injury rate.

Similarly, the requirement that the needles exit the lower abdominal wall is disadvantageous due to the trauma to the patient in this area and the pain of such abdominal wounds. A further disadvantage is that, as the tape is required to extend from the lower abdomen wall under the urethra and back through the lower abdomen wall, the tape must comprise a relatively large foreign body mass (typically around 25 to 28 cm) to be retained within the patient. This can lead to related inflammation,

infection translocation, erosion, fistula and such like.

Similarly, the nature of the large needles and tape, along with the tools required to insert these in the body, lead to the procedure having a relatively high cost.

Further details of the apparatus and methods of the prior art are provided in the co-pending International Patent Application No PCT/GB01/04554.

It would be advantageous if an implant such as a sling could be inserted into the body such that it is positioned loosely under the urethra without requiring penetration of the abdominal wall or rectus sheath. Most of the pain associated with previous procedures to introduce an implant as described above is due to the force required to penetrate the tough structures of the abdominal wall or rectus sheath, both of which are highly innervated. The suitable location of an implant such that it hangs loosely under the urethra without requiring penetration of the lower abdomen or rectus sheath would reduce the trauma experienced by the patient. Further, a greater number of major blood vessels are located in the retropubic space towards the rectus sheath than toward the endopelvic fascia and thus by suitably locating the implant, without piercing the rectus sheath, damage to these blood vessels would be minimised. This would reduce the amount of bleeding experienced by the patient.

In addition, such location of an implant with a reduced level of trauma may allow the procedure to be performed under local anaesthetic in an out patient or office setting.

Ideally an implant such as a sling used to treat female urinary incontinence includes means to adjust the position of the suburethral portion of the sling such that this portion passes under the urethra and is able to occlude the mid urethra at times of raised abdominal pressure. In addition, the implant should have minimal mass, when implanted in the body, to reduce the likelihood of inflammation and the like as discussed above.

According to the present invention there is provided a surgical implant for supporting the urethra, the implant including at least two fixing zones and a supporting zone, the supporting zone being interposed between the fixing zones and the fixing zones each having at least one retaining means for anchoring the fixing zones in the tissues of the retropubic space, without penetrating the rectus sheath such that in use the supporting zone passes under the urethra.

Preferably the fixing zones are anchored in the tissues of the retropubic space above the endopelvic fascia.

The retropubic space above the endopelvic fascia equates to the same pressure compartment as the intra-abdominal pressure compartment.

Preferably the retaining means are moveable from an inserting position to a retaining position.

Preferably the retaining means is at least one projection which can project from the implant into the tissues of the retropubic space in at least one plane the projection being moveable from a collapsed position to an extended position.

Where the retaining means are mechanical in nature in an inserting position the mechanical means are collapsed and in a retaining position the mechanical retaining means are in an extended position.

Where the retaining means are chemical in nature, for example glue in an inserting position the glue is in a state which minimises its adhesion to the surrounding tissue and in a retaining position the glue is in a state which allows the glue to adhere to the surrounding tissue. Thus in moving from a inserting position to a retaining position the presentation or the nature of the glue is changed to cause the glue to adhere the implant to the surrounding tissue.

The glue may be encapsulated (inserting position) within a capsule such that the glue cannot interact with the tissue during placement of the implant.

When the implant is suitably located, the capsule of glue may be burst (retaining position) to release the glue and allow the implant to be fixed to the surrounding tissue.

Alternatively the glue may be activated by some means, for example heat, light, cold or ultrasound. The implant can be moved into the retropubic tissue without the glue adhering the implant to the surrounding tissue (inserting position) then following the activation of the glue or change in state of the glue by some means, not limited to heat, light, cold or ultrasound, the glue will adhere the implant to the surrounding tissues (retaining position).

It is preferable if the implant has minimal mass to reduce the likelihood of inflammation or rejection of the implant when it is located in the body. Further, it is preferable that the implant comprises as little material as allows support of the urethra during periods of increased intra-abdominal pressure to minimise the abrasion or the urethra and the likelihood of adhesions forming at the urethra.

In addition, it is preferable if the fixing zone and the supporting zone are integral with each other as it allows easier manufacture of the implant. As the distance from the supporting region under the urethra to the fixing points in the retropubic space are relatively short in comparison to the distances between the supporting zone and the fixing zones

described in the implants of the prior art, the overall size of the implant can be reduced.

The production of an implant from a portion of tape material is preferable as it allows easier manufacture than implants comprising multiple portions comprising of different materials which have to be fixed together, it minimises the risk of failure of the implant due to the simplicity of the implant and provides for easier packaging and sterilisation of the implant.

It is preferable if at least one of the retaining means of the implant is moveable from a collapsed position to an extended position as it enables the retaining means to actively move into tissue in at least one layer of the tissue following suitable location of the implant. The movement of the retaining means from a collapsed position to an extended position allows the means to move into and be retained in tissue which was been undisturbed or which has not been disrupted during placement of the implant. The collapsed position of the implant can be achieved by rolling up, folding, bending, or enclosing the implant in a restrained position.

It is more preferable if the retaining means can be moved from a collapsed position to an extended position at two or more layers in the tissue as this provides for gripping of the tissue by the implant at multiple sites which may require increased force to be used to dislodge the fixing zones of the

implant from the anchored positions in the retropubic space.

The fixing zone of the implant must be anchored in the tissues of the retropubic space with adequate tensile strength to counter dislodging by coughing until suitable integration of tissue occurs.
At least two forces are exerted on the tape which extends under the urethra. A first force is the force exerted by the urethra during increased intra-abdominal pressure. The tape has to be secured in the retropubic space such that it is capable of supporting the urethra and occluding the urethra at periods of increased intra-abdominal pressure, to minimise incontinence.

A second force is the force exerted on the tape during periods of increased intra-abdominal pressure which acts in a direction opposite to the direction in which the fixing means are inserted into the retropubic space. This force can be considered to be a force of dislodgement.

Preferably the implant is anchored in the tissues of the retropubic space such that the implant can resist forces of dislodgement created during periods of increased intra-abdominal pressure.

Coughing and other causes of increased abdominal pressure typically cause increased pressures of around 200-400 cm water. This has been determined

by the Applicant to be equivalent to around a force of 3.75 N through each tape arm.

Preferably the implant is anchored in the tissues of the retropubic space such that the implant can resist forces of dislodgement created during periods of increased intra-abdominal pressure.of up to 3N.

More preferably the implant is anchored in the tissues of the retropubic space such that the implant can resist forces of dislodgement of up to 5N.

More preferably the implant is anchored in the tissues of the retropubic space such that it can resist forces of dislodgement of up to 10N.

Preferably each fixing zone comprises a plurality of retaining means.

Preferably the fixing zones are tapered

Preferably the retaining means comprise a plurality of projections extending laterally from the longitudinal axis of the implant.

More preferably the projections extend from the longitudinal axis of the implant such that they point away from the bladder when the implant is positioned such that the supporting zone passes under the urethra.

Preferably the projections are curved such that they point away from bladder when the implant is positioned such that the supporting zone passes under the urethra.

Preferably the implant is curved such that the longitudinal edges of the fixing zone of the implant and thus the retaining means in use are directed away from the bladder.

Curvature of the longitudinal edges of the fixing zone such that they are directed away from the bladder minimises medial presentation of the retaining means such as projections to the bladder minimising erosion of the bladder.

Preferably the fixing zone comprises the shape of a serrated arrowhead wherein the base portion of the arrowhead is conjoined to the supporting zone.

The serrated arrowhead can be provided by cutting a flat tape such that the serration's of the arrowhead exist in two dimensions only.

Preferably the fixing zone has a pointed end at a first end, a base portion at a second end, wherein the longitudinal edges extend between the pointed end and the base and the longitudinal edges are notched to provide a row of projections extending outward from the longitudinal edges.

In other words the fixing zone has a pointed tip at a first end and a base portion at a second end, the first end being the end of the fixing zone furthest from the supporting zone the base portion being conjoined to the supporting zone. The longitudinal edges of the fixing zone extending from the pointed tip to the base wherein the longitudinal edges are notched to from a row of tooth like projections extending from the longitudinal edge.

Alternatively the retaining means is glue.

Preferably the glue is cyanoacrylate glue.

More preferably the glue is held in a releasable container. The glue containing releasable container may prevent the glue interacting with surrounding tissues until an appropriate point in the surgical procedure. At this point the surgeon may use means, for example a point on the introducing tool to release the glue from the container, for example by puncturing the container and enabling the glue to adhere the implant to the surrounding tissue.

Preferably the implant is comprised of resilient material such that if the implant is not restrained it adopts the original shape defined during production of the implant.

Preferably the implant is comprised of plastics material.

More preferably the implant is comprised of polypropylene.

Preferably the implant is comprised of non-absorbable material.

Alternatively the implant is comprised of absorbable material.

It would be advantageous if the implant was capable of longitudinal extension such that it still provides suitable support to the urethra during periods of increased abdominal pressure, but is able to move and extend in a similar fashion to tissues which physiologically support the urethra.

Preferably the implant further comprises a resilient zone wherein the resilient zone provides for the resilient extension of the tape such that the tape behaves in a similar manner to dynamic bodily tissue.

Preferably the resilient zone is located in at least one of the fixing zones of the implant.

Alternatively the resilient zone is interposed between the fixing zone and the supporting zone.

Preferably the resilient zone of the implant is capable of allowing the resilient extension of at least part of the implant due to its geometric design.

Alternatively the resilient zone of the implant is capable of allowing resilient extension of at least part of the implant due to its micro material design.

More preferably the resilient zone of the implant is capable of allowing the resilient extension of the implant due to a combination of its geometric and micro material design.

Preferably the geometric design includes multiple strips of material.

More preferably the geometric design includes multiple strips of material arranged into bows, the bows being capable of deforming and providing resilient extension to the implant.

Alternatively the geometric design comprises a concertina portion such that a part of the implant can extend in a direction substantially perpendicular to the folds of the concertina.

In other words the implant comprises a folded portion, the fold perpendicular to the longitudinal axis of the implant, which allows limited extension of the implant in a longitudinal direction. In an extended position a folded portion is moved away from a second folded position. In a closed portion the folded portions are brought together. Different amounts of force in a longitudinal direction may be

required to move the concertina portion from a closed to an open position.

Preferably resilient extension of a portion of the implant occurs when an extension force of 1 to 5 N is applied to the implant along its length.

Preferably resilient extension of a portion of the implant occurs when an extension force of 2 to 3 N is applied to the implant along its length.

Preferably the resilient zone provides for the extension of the implant along its longitudinal length of around 2 to 5 mm.

Preferably the unextended implant is of length 6 to 22 cm.

More preferably the unextended implant is of length 8 to 20 cm.

Most preferably the surgical implant is of unextended length 10 to 15 cm.

Preferably each fixing zone is of at least 1 cm in length and not greater than 8 cm in length.

More preferably each fixing zone is 5 cm in length.

Preferably the supporting zone is of at least 2 cm in length.

Preferably the tape of the supporting zone is a mesh.

Preferably the mesh is resilient.

Preferably the mesh is resilient to such an extent that it mimics the physiological elasticity of tissues which would normally support the urethra.

Preferably the mesh comprises strands and includes major spaces and pores, the major spaces existing between the strands and pores formed within the strands.

Preferably the strands are formed from at least two filaments.

Preferably the strands are spaced apart to form major spaces of 1 to 10mm.

Preferably the strands have a diameter of less than 600μm.

Preferably the strands are arranged to form a warp knit diamond or hexagonal net mesh.

Preferably the filaments comprise a plastics material for example polyester or polypropylene.

More preferably the filaments are absorbable. The mesh may be encapsulated by an absorbable or non

absorbable coating or a coating may be applied to at least one side of the implant.

The surface material may be polylactic acid and the core material may be polypropylene.

The mesh may be formed from biocomponent microfibres comprising a core and surface material. The surface material may be readily absorbable by the body while the core material may remain in the body for a longer period of time.

The supporting zone of the implant may be absorbable at a different rate than the fixing zones of the implant, for example the supporting zone may be absorbed within six weeks of implantation, while the fixing zones may remain for 9 months.

Preferably the fixing zones remain in the body longer than the supporting zone.

The fixing zones are required to remain in the body until increases in intra-abdominal pressures, for example due to coughing, laughter, straining, sneezing or lifting a heavy object, are transmitted to the pressure compartment which includes the urethra such that the increased intra-abdominal pressure promotes occlusion of the urethra.

Preferably pressure transmission occurs when a pubourethral neoligament forms.

Generally formation of the pubourethral neoligament takes place in around 6 -9 months.

Intra-abdominal pressure transmission to the pressure compartment which includes the urethra may be provided by suitable placement of anchor strips comprising fixing zones on either side of the urethra, such that when at least one anchor strip is suitably positioned on either side of the urethra, even although the anchor strip does not pass under the urethra and directly support the urethra using a supporting element, the anchor strip provides sufficient support to the urethra, by connecting the intra-abdominal pressure compartment and sub urethral pressure compartment such that increases in intra-abdominal pressures are transmitted to the urethra, promoting occlusion of the urethra during periods of increased intra-abdominal pressure.

According to a further aspect of the present invention there is provided at least one anchor strip comprising at least one fixing zone having at least one retaining means wherein in use a first portion of the anchor strip is retained in the tissues of the retropubic space above the endopelvic fascia and a second portion of the anchor strip extends into the urethral pressure compartment below the endopelvic fascia and thereby supports but does not pass under the urethra.

The sub urethral space is defined as a pressure compartment below the endopelvic fascia.

Preferably the anchor strips are between 2 cm and 8 cm in length.

More preferably the anchor strips are between 4 cm and 8 cm in length.

Most preferably the anchor strips are 6 cm in length.

The fixing zones of the anchor strip include retaining means as described herein.

Preferably the anchor strips comprise any of the

Preferably the implant is of width 0.3 to 1.7 cm.

More preferably the implant is of width 0.5 cm to 1.5 cm.

Most preferably the implant is of width 1.0 cm to 1.1 cm.

Preferably the implant is of thickness 100μm to 300μm.

More preferably the implant is of thickness 200μm.

Where the implant is reinforced, the material of the implant may be of double thickness. In reinforced areas of the implant the implant may be of thickness between 200μm to 600μm. More preferably the

reinforced areas of the implant are of thickness 400μm.

The implant is of suitable length such that a first fixing zone can be secured in the tissues of the retropubic space and the implant can extend from the tissues of the retropubic space, pass on one side of the urethra such that the supporting zone of the implant passes under the urethra and a second fixing zone passes on the other side of the urethra and into the tissues of the retropubic space, such that the second fixing zone can be secured in the tissues of the retropubic space. Preferably the fixing zones are positioned only as far into the tissues of the retropubic space as required such that pressure transmission occurs and the mid-urethra is occluded at periods of raised abdominal pressure such as coughing.

Typical cough pressures generated are around 0 to 150 cm water. Maximum cough pressures generated are 200 cm to 400 cm of water.

Thus during periods of raised abdominal pressure, such as coughing, the bladder and urethra are pushed downwards. The tape acts against this downward movement of the urethra supporting the urethra and causing the mid urethra to be occluded. This minimises incontinence. If the tape further comprises resilient zones, the resilient extension of the tape during periods of raised abdominal pressure cushions the urethra against the force

subjected to the urethra by the tape, such that the urethra is supported in a more similar manner as provided by physiological tissues. However, the force subjected to the urethra by the tape comprising resilient means, still causes the mid urethra to be occluded at periods of raised abdominal pressure and minimises incontinence.

It is preferable that tissue growth around and through the implant occurs to integrate the implant into the body.

Fibroblastic through growth around the implant secures the implant in the body increasing the support provided by the implant.

Preferably at least one of the fixing zones of the implant is provided with means to improve fibroblastic through growth into the implant.

Preferably the means to improve fibroblastic through growth comprises pores which extend through the fixing zone material said pores ranging in width across the surface of the fixing zone from 50μm to 200μm.

More preferably the pores are a width of 100 μm.

Alternatively the means to improve fibroblastic through growth comprises pits, that indent at least one surface of the fixing zone, but do not extend

through the fixing zone, the pits ranging from 50 to 200 μm in width.

More preferably the pits are 100 μm in width.

As a further alternative, the means to improve fibroblastic through growth comprise slits that extend through the fixing zone material said slits being 2mm in length and 500μm in width.

Preferably the slits are 1mm in length and 100μm in width.

More preferably the slits are 200μm in length and 50μm in width

Preferably the pits, pores or slits are distributed across the complete surface of at least one of the fixing zones.

Alternatively the pits, pores or slits are distributed only in a particular portion of the surface of at least one of the fixing zones.

Preferably the pits, pores or slits are created by post synthesis treatment of at least one of the fixing zones by a laser.

Alternatively the pits, pores or slits are created during synthesis of at least one of the fixing zones.

Where the fixing zone is comprised of plastics material the pits, pores or slits may be formed by the spaces of mono-filament between the waft and weave of mono-filament or multi-filament yarns when the filaments are woven to form a mesh.

Alternatively pits, pores or slits formed during the synthesis of plastics material are formed by the inter-filament spaces created when mono-filaments are twisted to create multi-filaments, the multi-filaments then being woven to form a mesh.

Preferably integration of the implant into the body via fibrous tissue through-growth begins to occur within one month of insertion of the implant in the body.

More preferably integration of the implant into the body via fibrous tissue through-growth begins to occur within two weeks of insertion of the implant in the body.

It is also advantageous that lay down of collagen fibres occurs in an ordered direction to promote the formation of at least one strong ordered neoligament. The formation of at least one ordered neoligament aids the support of the urethra provided by the implant by adding mechanical strength to tissue which forms around the implant.

Preferably at least one of the fixing zones is provided with at least one microgroove on at least one surface of the fixing zone.

Preferably at least one of the fixing zones is provided with a plurality of microgrooves on at least one surface of the fixing zone.

Preferably a microgroove is of width between 0.5 μm to 7 μm and of depth 0.25 μm to 7 μm.

More preferably a microgroove is 5 μm in width and 5 μm in depth.

Preferably the plurality of microgrooves are aligned such that they are substantially parallel with each other.

Preferably the plurality of microgrooves are aligned such that they are separated by ridges which range in size between 1 μm to 5 μm in width.

More preferably the microgrooves are separated by ridges of 5 μm in width.

Preferably the ridges are formed by square pillars and the base of the microgroove is substantially perpendicular to the square pillars.

Alternatively the ridges are formed by square pillars and the base of the microgroove is bevelled in relation to the pillars.

Preferably the microgrooves are present on at least one surface of the fixing zone.

More preferably the microgrooves are present on a plurality of surfaces of the fixing zone.

Preferably the supporting zone of the implant does not comprise pores or pits.

Preferably only the surfaces of the supporting zone not brought into contact with the urethra comprise microgrooves.

The supporting zone is not provided with pores or pits to discourage the formation of peri-urethral adhesions.

Preferably at least one fixing zone is capable of being moved in and out of the tissues of the retropubic space by a surgeon.

Preferably movement of the fixing zone into and out of the tissues of the retropubic space allows adjustment of the location of the supporting zone such that it passes under the urethra.

Preferably the supporting zone comprises a marker to aid the suitable location of the supporting zone under the urethra.

More preferably the marker is a wider portion of tape of the supporting zone that indicates the midpoint of the supporting zone.

The tape may comprise a reinforced portion. This is advantageous as it allows the bulk of the tape to be formed from a minimal mass of material. Regions of the tape which require tensile strength can be then strengthened appropriately.

Preferably the spine of the tape running along the longitudinal axis can be reinforced.

Reinforcing may be provided by using a double thickness of material.

Preferably each fixing zone comprises at least one aperture adapted to receive and co-operate with a tool for insertion of the implant into the body.

Preferably the tape surrounding the aperture is of double thickness. This is advantageous as it provides additional strength to the tape in this region.

More preferably the aperture is bound by ultrasonic welding.

Preferably the aperture is located towards the end of the fixing zone furthest from the supporting zone.

Preferably the implant is used to support the urethra.

Preferably the implant is used for treating urinary incontinence or uterovaginal prolapse.

The invention also provides a tool for inserting the implant into the body the tool comprising an elongate shaft including a semi-blunt point at a first end and a handle at a second end and holding means to releasably attach the shaft to the implant.

Preferably the tool can be used to insert implants comprising a supporting zone or anchor strips.

Preferably the elongate shaft is curved or bent, through an angle of approximately 30°.

Preferably the elongate shaft of the tool is of length 6 to 15 cm.

More preferably the elongate shaft of the tool is 8 cm in length.

Preferably the elongate shaft of the tool is between 2-3 mm in diameter.

Preferably the holding means comprises a recess extending from the semi-blunt point of the elongate shaft the recess capable of receiving a portion of the implant.

The point of elongate shaft comprising the recess may be offset such that a first portion forming a wall of the recess is longer than a second portion forming the opposite wall of the recess. This is advantageous as the longer portion of the shaft on one side of the recess aids mounting of the tape on the tool.

Preferably the recess is angled to twist an implant received by the recess along its longitudinal length such that the longitudinal edges of the fixing zone of the implant are directed away from the bladder.

Twisting of the implant such that the edges of the fixing zone are directed away from the bladder minimises medial presentation of the retaining means to the bladder.

Alternatively the holding means comprises an abutment located toward the first end of the elongate shaft of the tool wherein the semi-blunt point of the elongate shaft is capable of being passed through the implant and the abutment is capable of hindering movement of the implant down the length of the shaft toward the second end of the elongate shaft.

Preferably the tool is comprised of plastics material.

Alternatively the tool is comprised of surgical steel.

Preferably the handle is circular in shape and is mounted perpendicular to the curvature at the second end of the elongate shaft.

According to a further aspect of the present invention there is provided a method of supporting the urethra comprising the steps of;

introducing an implant into a least one incision made on the upper wall of the vagina,

inserting a first end of the implant behind the first side of the urethra,

locating a first fixing zone into the tissues of the retropubic space without penetrating the rectus sheath,

inserting a second end of the implant behind a second side of the urethra, and

locating a second fixing zone into the tissues of the retropubic space without penetrating the rectus sheath, such that the supporting zone passes under the urethra.

Preferably the ends of the implant are located in the retropubic space above the endopelvic fascia.

Preferably the method further includes the step of moving the retaining means from an inserting position to a retaining position.

Preferably the method of supporting the urethra is used in treating urinary incontinence or uterovaginal prolapse.

According to a further aspect of present invention there is provided a method of transmitting intra-abdominal pressure to the urethra comprising the steps of

introducing an anchor strip into at least one incision made on the upper wall of the vagina;

inserting a first portion of the anchor strip behind the first side of the urethra;

locating a first portion including a fixing zone into the tissues of the retropubic space above the endopelvic fascia without penetrating the rectus sheath;

locating a second portion of the anchor strip alongside the urethra in the suburethral pressure compartment below the endopelvic fascia ;

inserting a second anchor strip behind a second side of the urethra;

locating a first portion including a fixing zone of the second anchor strip into the tissues of the retropubic space without penetrating the rectus sheath; and

locating a second portion of the second anchor strip along side the urethra in the suburethral pressure compartment below the endopelvic fascia.

Preferably at least one anchor strip is introduced through two small incisions.

Preferably the method further includes the step of moving retaining means from an inserting position to a retaining position.

Preferably the anchoring strip is used to treat urinary incontinence or uterovaginal prolapse.

Preferably the method of enabling transmission of the intra-abdominal pressure to the urethra is used in treating urinary incontinence or uterovaginal prolapse.

Embodiments of the present invention will now be described by way of example only, with reference to the accompanying drawings in which;

Figure 1 shows a diagrammatic view of the implant;

Figure 2 shows a diagrammatic side view of the implant;

Figure 3 shows retaining means which may be present at the fixing zone;

Figure 3b shows an illustration of one embodiment of the tape in cross section;

Figure 3c shows an illustration of a further embodiment of the tape;

Figure 4 shows an illustration of a further embodiment of the tape wherein the supporting zone is formed from mesh;

Figure 5 shows a diagrammatic view of the retropubic space, related to needle passage for any pubo-vaginal sling;

Figure 6 shows an illustration of an introducing tool;

Figure 7 shows an illustration of a further embodiment of an introducing tool wherein the point of the tool is offset to aid insertion of the implant into the recess of the tool;

Figure 8 shows an illustration of a further embodiment of an introducing tool;

Figure 9 shows an illustration of the position of the tape in relation to the bladder taken from a superior view; and

Figures 10a and 10b show alternative embodiments of retaining means.

Figure 11 shows anchor strips positioned on either side of the urethra in the suburethral space below the endopelvic fascia and extending into the retropubic space above the endopelvic fascia.

Referring to figure 1 in one embodiment the surgical implant is a flat tape 2 which has a supporting zone 4 interposed between two fixing zones 6, the fixing zones being discrete zones of fixation extending from the supporting zone 4 to the first 8 and second 10 ends of the tape 2 respectively. Apertures 11 extend through the tape 2 approximate to the first and second ends of the tape 2. These apertures 11 are of suitable size to allow a portion of an introducing tool to be passed through the apertures 11.

The implant may be 14 cm in length and 1 cm in width, the supporting zone 4 being around 4 cm in length such that it is able to pass under the urethra.

In this example, the implant is made from flat polymer tape. The tape may be comprised of polypropylene. Alternatively all or portions of the tape can be mesh material. The tape need not be entirely flat and may have be curved in one or more directions for example to aid insertion of the tape or to ensure that the fixing zone does not interfere with elements contained in the retropubic space such as the bladder.

As shown in figure 3 the longitudinal edges 30, 32 of the fixing zone 6 may be tapered such that the width of the fixing zones increases from the first and second ends 8, 10 of the fixing zones to the supporting zone. The tapered nature of the fixing zones 6 minimises disruption of the tissue of the retropubic space during placement of the tape 2 by the surgeon. The increasing width forms an arrowhead shape, the longitudinal edges of the tape extending from a point at a first and second end of the tape to the longitudinal edges of the support zone. The longitudinal edges extending from the point to the supporting zone may be serrated or notched to provide projections 22 which in use extend into the tissues of the retropubic space. The projections 22 provide multiple points of contact between the tape 2 and the tissues of the retropubic space at multiple planes in the tissue.

The projections 22 of the retaining means 20 in the embodiment shown in figure 3 are curved such that

they extend from the longitudinal axis such that in use the projections 22 are not medially presented to the bladder 42 which lies anterio-medially in respect to the passage of tape 2 in the body.

Further as shown in figure 3b the tape 2 may be of curved or of convex construction such that retaining means 20 such as the projections 22 face in a direction opposite or away from the bladder 42 in use. The curvature of the tape 2 therefore ensures that the projections 22 lie postero-laterally of the anterio-medial bladder position. This positioning minimises the possibility of bladder erosion by the tape 2 following placement.

The tape 2 of the supporting zone has smooth longitudinal edges to avoid adhesion of the supporting zone of the tape to the urethra.

This is advantageous as it discourages the formation of peri-urethral adhesions.

The polypropylene tape 2 of the fixing zone 6 comprises pores 12, ranging in width from 50μm to 200μm, that extend through a first surface 14 to a second opposite surface 16 of the tape 2. The pores 12 may be formed by post synthesis treatment of the fixing zones of the tape 2 with a laser.

The pores 12 promote fibroblastic through-growth and lay down of tissue around and through the tape 2.

This aids integration of the fixing zone of the tape 2 to the tissue of the retropubic space.

The pores 12 may alternatively be created by post synthesis treatment of the fixing zones 6 of the tape 2 by a laser.

In addition to the pores 12, in the embodiment shown the fixing zone also comprises microgrooves 18 of width 5μm and of depth 5μm. These microgrooves 18 are shown present on one surface 14 of the fixing zone of the tape 2, but may also be present on the opposite surface. In the embodiment shown the microgrooves 18 are aligned such that they are substantially parallel with each other and separated by ridges 24 of around 5μm in width. It can be appreciated that the micogrooves may be arranged to create alternative surface patterns on the tape, depending on the direction of the laydown of tissue preferred.

The ridges 24 are formed by square pillars, the base 26 of the microgroove 18 being substantially perpendicular to the square pillars.

Microgrooving can promote orientation and alignment of proliferating fibroblasts on the surface 14 of the tape 2 of the fixing zone 6 and promotes axial alignment of collagen fibres and formation of at least one strong ordered neoligament. The orientation and alignment of the proliferating cells adds mechanical strength to the tissue which form-

around the tape such that these tissues support the urethra.

The supporting zone 4 of the tape 2 is preferably not provided with pores or pits to discourage the formation of peri-urethral adhesions. Micro-grooving is preferably provided only on the surfaces of the supporting zone not brought into contact with the urethra when the implant is in use.

As discussed, urinary incontinence may be caused if the pelvic floor muscles and connective tissue cannot support the bladder neck and mid-urethra, when pressure on the bladder is exerted from the diaphragm. Increased intra-abdominal pressure may occur at times such as coughing. The increased abdominal pressure results in the urethra descending from its normal position and failing to retain its seal, permitting urine to escape.

Previous apparatus and methods used for locating an implant such that the implant hangs loosely under the urethra have generally required that the implant be suspended from either the lower abdominal wall, the rectus sheath or other defined anatomical support structures. The suspension of an implant from defined anatomical support structure was thought necessary as the tissues of the retropubic space and endopelvic fascia were not deemed to provide enough resistance to allow appropriate location of an implant such that suitable support would be provided to occlude the mid-urethra at

periods of raised abdominal pressure, by coughing or the like.

Surprisingly the Applicant has determined that suitable support can be provided by the tissues of the retropubic space, if fixation of the implant is achieved in the tissues of the retropubic space. Due to the tissue make up of the retropubic space, it was not previously considered that suitable fixation could be achieved in the retropubic space. Further it was not considered that suitable pressure transmission would be achieved to occlude the urethra, using a tape suspended from the tissue of the retropubic space, doing periods of increased abdominal pressure.

As shown in figure 7 the retropubic space 40 is an extraperitoneal tissue space lying behind the pubic bone. The retropubic space is defined by an anterio -superior boundary which is the peritoneum and rectus sheath 44 and an interior boundary of endopelvic fascia 46. The space defined by these boundaries is medially filled by the bladder 42, the urethra 48, fibro-fatty tissue and blood vessels. The blood vessels of the retropubic space generally become larger both in a superior and lateral direction within the retropubic space. The retropubic space approximately extends 8 cm from the endopelvic fascia to the rectus sheath, this distance varying by around 2 cm depending on the individual. The retropubic space comprises the same pressure compartment as the abdomen.

To locate the supporting zone 4 such that it passes loosely under the urethra 60 it is required that the fixing zones 6 are fixed in the tissues of the retropubic space 40 with as little tissue invasion as possible, but such that pressure transmission to the tape is maintained. A number of different retaining means can be envisaged including a christmas tree design (a), a brush (b), a fish hook (c), a triple hook (d), an umbrella (e), one or more rods with memory (f), a corkscrew (g), an inflatable balloon (h), an inflatable flat star (i), a bear trap (j), a bulldog clip (k), a mesh cylinder (l), a buckie ball (m), a staple (n), a barbed portion of tape (o), a sponge (p) or fibre entanglement method (q) to secure the fixing zones of the surgical implant into the tissues of the retropubic space. Examples of these embodiments are shown in figures 10a and 10b. It should also be noted that a plurality of retaining means may be located alone or in combination along a substantial part of the fixing zone.

As shown in figure 11 support to the urethra can be suitably gained by locating at least one anchor strip 80 on either side of the urethra such that a first portion of the anchor strip 82 extends into the retropubic space above the endopelvic fascia and is retained therein and a second portion of the anchor strip is located in the suburethral pressure space below the endopelvic fascia such that increases of intra-abdominal pressure are

transmitted to the pressure compartment containing the urethra and during periods of increased intra-abdominal pressure the urethra is occluded minimising incontinence. Retention of the first end of the anchor strip in the retropubic space is provided by retaining means.

In a first embodiment, retaining means 20 are a plurality of projections 22 extending laterally from the longitudinal axis of the implant. These projections 22 are arranged along a substantial portion of the length of the fixing zone 6 such that when located in the tissues of the retropubic space they provide resistance at multiple levels within the fibro-fatty soft tissue and blood tissues of the para-urethral tunnel in a direction opposite to that in which the fixing zone 6 of the tape 2 is introduced into the tissues. This minimises movement of the tape out of the tissues of the retropubic space, even when a force is applied to the tape which acts to push or pull the tape out of the retropubic space.

Due to the multiple layers of fixation that can be achieved using the plurality of retaining means 20 along a substantial length of the fixing zone 6 it is not necessary to insert the fixing zone through the rectus sheath 44. This of significant advantage to the patient as puncture of the retropubic space requires considerable force by the surgeons and also requires larger, heavier needles leading to patient trauma. In addition the tissues around the rectus

sheath are inervated leading to pain if these are punctured. The fixing zone 6 is movable within the tissues of the retropubic space by the surgeon during placement of the tape 2 to allow suitable positioning of the supporting zone 4 under the urethra. The retropubic space maximum sagittal length typically ranges between 6 cm to 10 cm defined by the boundaries discussed, thus the fixing zone 6 may be inserted at various positions within the fibro-fatty tissue of the retropubic space. The sagittal plane is that down the longitudinal length of the body. The approximate 8 cm length is the typical length of the retropubic space at the course of the paraurethral tunnel. Towards the pubic bone the retropubic space may be only 3 cm in length. This provides a means of adjustment of the position of the supporting zone 4 in relation to the urethra. The tape 2 may be moved by a surgeon during placement of the tape in the body into and out of the tissues of the retropubic space to suitably locate the supporting zone in relation to the urethra.

As shown in figure 3 the projections 22 which form the retaining means 20 are curved such that the points 24 of the projections 22 are directed away from the supporting zone and the bladder.

In a further second embodiment of the implant as shown in figure 3c, the implant further comprises resilient zones 7 interposed between the fixing zones 6 and the supporting zone 4.

The two resilient zones 7 may comprise a geometric design of several strip portions conjoined at a first end to the supporting means and at a second opposite end to fixing means on the implant.

When not under tension these strip portions of tape material are bow shaped and are arranged such that they form a series of alternate and side by side convex and concave strips arranged in substantially the same plane as the tape.

On application of an extending force of up to 3N to the tape along its length, the tape can show 2-3 mm of extension, as the bowshaped portions of the tape are pulled into straight strips, the ends of the bowshaped strips being brought together, enabling extension of the tape. The movement of the tape from the resting bowshape into the tensioned straight strips of tape allows the tape to resiliently extend along its length.

The maximum length to which the tape can be extended, is when the convex and concave portions of the tape are pulled such that these strips are brought into alignment with the longitudinal axis of the implant. Depending on the nature and length of the bow shaped portion, the extended length and the force required to promote extension of the tape can be controlled.

On release of the extending force these now straightened strips of tape of the resilient zone return to their previous non-extended bowshape causing the tape to resiliently return to its non-extended length.

The ability of the tape to show limited extension following the application of an extending force means that the tape more accurately mimics the movement of dynamic bodily tissue.

In order that the bowshape like portions of the tape can be pulled such that they are straightened, the material of the tape must be resilient to an extent, The amount of resilience of the material will influence the resilience of the tape to an extending force. In addition, the micro material design of the material of the tape can be used to limit or promote the resilience of the tape to an extending force.

Micro material design includes the way in which the tape material is woven, knitted of formed such that the tape material is resilient and allows extension along a particular axis.

Different geometric designs to allow extension of the implant in particular directions can be envisaged, for example folding of the tape would provide a concertina design which would allow resilient extension of the table in a direction substantially perpendicular to the folding.

This further embodiment of the implant shown in figure 3C also shows elongate slits in the fixing means of the tape. These elongate slits are of 1 mm in length and 50 to 100μm in width. The elongate slits allow fibroblast through growth into the tape, securing the tape to the tissues.

As shown in figure 3c the implant can further comprise a protrusion of fabric 9 which extends laterally from the longitudinal edges of the supporting zone member to indicate to the surgeon the midpoint in the length of the tape to aid the surgeon in locating the implant under the urethra.

The inclusion of the resilient zones within the implant, shown in figure 1, provides the implant with limited extension following location of the fixing zones in the retropubic tissues on either side of the urethra. As the supporting zone which lies underneath and supports the urethra can show limited extension, the urethra is therefore supported in a more similar manner to that as when it is supported by dynamic bodily tissue.

The embodiments of the implant described herein may be suitably located in the tissues of the retropubic space using an introducing tool.

As shown in figure 6 one embodiment of the introducing tool 50 comprises a handle 52, an elongate shaft 54 and a semi-blunt point 56, the

handle 52 being located at a first end 58 of the elongate shaft 54 and the semi-blunt point 56 being located at a second end 60 of the elongate shaft 54. The elongate shaft 54 is curved through an angle of approximately 30° to facilitate positioning of the fixing zone 6 of the implant in the tissues of the retropubic space of the human body from an incision in the upper wall of the vagina. A narrowed portion 62 of the elongate shaft 54 extends from the semi-blunt point 56 toward the handle 52. An abutment 64 is formed where the shaft widens from the narrowed portion. The narrowed portion of the tool is able to be passed through the aperture 11 present in the fixing zones 6 of the tape 2. The abutment 64 prevents the movement of the tape 2 down the full length of the elongate shaft 54 such that the tape 2 is retained on the narrowed portion 62 of the elongate shaft 54, the semi-blunt point 56 extending through the aperture 11 in the tape 2.

An alternative embodiment of the tool, shown in figure 7 comprises a recess 70 which extends from the semi-blunt point 56, the recess being adapted to receive a fixing zone 6 of the implant. The recess may be angled or offset such that when the fixing zone of the tape is positioned in the recess 70 of the tool, the tape is twisted along its longitudinal length such that on placement of the tape within the tissues of the retropubic space the projections of the fixing zone face postereo-laterally of the anterio-medial bladder position. Figure 8 shows an

illustration of the direction of the retaining means in relation to the bladder.

Further the tip of the tool may be offset such that one portion forming the wall of the recess extends further than the other portion forming the recess. This allows easier positioning of the tape into the recess.

The introducing tool 50 may be comprised of any suitable material. In the embodiments shown the tool 50 is 8 cm in length and 2-3 mm in diameter and is comprised of hard plastic. The tool may be disposable or capable of being sterilised.

With regard to the first embodiment of the tool, in use the semi-blunt point 56 is passed through the aperture 11 in the tape 2 such that the tape 2 rests on the abutment 64 preventing the tape 2 from moving further down the elongate shaft 54 of the tool 50. The tape 2 is rolled about its longitudinal axis such that the edges 30,32 are brought toward each other. The tape 2 is restrained in this rolled position. The tape 2 may be restrained by the surgeon or by an envelope placed over the rolled tape. An envelope placed over the rolled tape may comprise a medial defect, which allows removal of the envelope when the tape is suitably positioned, by pulling the tape through the defect in the envelope.

The rolled fixing zone 6 of the tape 2 is inserted via an incision in the anterior vaginal wall, past one side of the urethra and into the retropubic space. Ideally insertion of the fixing zone 6 into the tissues of the retropubic space should be as limited as possible, but sufficient to allow suitable location of the fixing zone 6 and adequate pressure transmission to allow occlusion of the urethra. Following insertion of the first end of the tape 2, the fixing zone 6 may be moved within the tissues of the retropubic space by the surgeon such that the fixing zone 6 is suitably located in the fibro-fatty soft tissue. Withdrawal of the introducing tool 50, described above, causes the narrowed portion 62 of the tool 50 to be retracted from the aperture 11 of the tape 2. This causes release of the tape 2 from the tool. The tape may also be released from its restrained position by the surgeon. As the implant is formed from resilient material, which has memory, release of the implant from its restrained rolled position causes the longitudinal edges 30,32 to expand outwards, away from each other, from the rolled position such that the retaining means, the plurality of projections 22 at multiple layers, are pushed into the surrounding tissues of the retropubic space.

This causes projections to enter the retropubic tissue at multiple levels. Although the force required to move one projection through the tissue of the retropubic space may be small, the multiple projections, cause an additive effect and increase

the force required to move the tape from the tissue of the retropubic space.

With regard to the second embodiment of the introducing tool discussed, in use, an aperture 11 in the tape 2 is passed over the semi-blunt point 56 such that a portion of fixing zone 6 of the tape 2 is retained in the recess 70, while the rest of the tape 2 comprising the supporting zone and a second fixing zone lies along the longitudinal length of the tool. As discussed, the recess 70 of the introducing tool may be angled such that the fixing zone 6 retained within the recess 70 is orientated such that on placement of the fixing zone 6 in the tissues of the retropubic space the retaining means 20 of the fixing zone 6 face away from the bladder to minimise the risk of erosion of the bladder by the retaining means.

Introduction of the implant into the body using the second embodiment of the tool described is similar to that previously described. Release of the fixing zone 6 of the tape 2 from the recess 70 is performed by withdrawal of the tool.

The serrated arrowhead shape of the fixing zone of the embodiment described, means that as the fixing zone is pushed into a suitable location by the surgeon using the introducing tool, the distortion of the tissue in which the fixing zone is to be placed is minimised. This ensures that the retaining means of the fixing zone is provided with

suitable tissue in which to obtain multi-level fixation. The fixation being of adequate tensile strength against cough until fixation of the implant by tissue through-growth occurs.

Following insertion and suitable placement of the fixing zone 6 of the tape 2, penetration of the fibro-fatty tissue by the multiple projections 22 occurs at multiple levels in the tissue and increases the grip of the retaining means 20 on the fibro-fatty soft tissue of the retropubic space. As the entry of the retaining means 20 is active and not passive, actively inserting the retaining means 20 into the tissue, the gripping effect of the plurality of the projections 22 is increased.
A second fixing zone comprising retaining means 20 as described for the first fixing zone is rolled such that the longitudinal edges 30,32 are brought toward each other. The implant is restrained in this rolled position and inserted through the same incision in the vaginal wall as the first fixing zone, past the other side of the urethra to that of the first fixing zone and the rolled second fixing zone 6 released to allow the retaining means to grip the tissues of the retropubic space. The supporting zone 4 of the tape 2 being suitably located and held in position by the fixing zones 6 under the urethra to provide support to the urethra. In such a suitable portion the supporting zone is able to occlude the urethra at periods of increased abdominal pressure and thus minimise urinary incontinence.

In a second embodiment of the present invention retaining means are provided by glue.

Suitable glue such as cyanoacrylate glue or butyl acrylate glue may be applied to the fixing zone 6 of the tape 2. The glue is not applied to the supporting zone 4 of the tape 2, to ensure that the supporting zone 4 does not bind to the urethra.

In use cyanoacrylate glue is applied along a substantial length of a first fixing zone 6 of the tape 2 and this first fixing zone 6 is inserted through an incision in the anterior vaginal wall, past one side of the urethra into the retropubic space. Following insertion of the first end 8 of the implant such that the fixing zone 6 is suitably located in the fibro-fatty soft tissue of the retropubic space, the tape 2 is held to enable an adhesive bond to form between the fixing zone 6 of the tape 2 and the tissues of the retropubic space. As the glue is applied along a substantial length of the first fixing zone 6, the first fixing zone 6 adheres to the fibro-fatty soft tissue of the retropubic space at multiple layers providing suitable resistance.

Cyanoacrylate glue can then be applied along a substantial portion of a second fixing zone 6. The second fixing zone 6 can then be inserted through the same incision in the vaginal wall and past the other side of the urethra such that the supporting

zone 4 is located to provide support to the urethra. The glue may be provided within dissolvable spheres which will coat the glue during entry of the tape into the body, the coating dissolving when the implant is suitably located such that the glue can adhere the tape to surrounding tissues.

The glue to adhere the fixing zones of the implant to the tissues of the retropubic space may be provided in capsules or releasable containers mounted or attached to the implant. Once at least one of the fixing zones of the implant has been suitable positioned in the tissues of the retropubic space the capsules containing the glue can be burst using suitable means. For example, the capsule may be burst using a sharp point present on the introducing tool. Alternatively withdrawal of the introducing tool from the retropubic tissues may rupture or burst such capsule or promote the opening of the releasable containers such that the glue contained in the capsule or container is able to adhere the fixing zone of the implant to the surrounding tissues.

Where glue is use to adhere the fixing zone of the implant to the surrounding tissue, the fixing zone may be smaller than the dimensions listed above. Use of glue to fix the implant in the tissues of the retropubic space provides multilevel fixation of the implant. Other methods or means to allow release or activation of the glue, for example heat, can be envisaged by those skilled in the art.

Further embodiments of retaining means can be envisaged such as swelling hydrogels such as gelatin, polysaccharides or Hyaluronic acid. These may be applied to the fixing zone 6 of the implant, such that following introduction of the fixing zone 6 of the implant into the body the hydrogel expands, providing resistance in a direction opposite to that in which the fixing zone 6 of the implant is introduced into the tissues, suitably locating the supporting zone 4 to support the urethra.

In addition retaining means may be substances which have properties changed by heat, cold or light that may be applied to the fixing zone 6 of the implant such that on suitable treatment of the implant, the fixing zone 6 of the implant becomes suitably fixed in tissues of the retropubic space.

The length of the implant of the present invention is considerably less than that described in the prior art, which is typically 25 to 28 cm in length. This is of considerable advantage as the amount of foreign material placed in the body is reduced, decreasing the risk of inflammation and other problems associated with leaving foreign material in the human body for periods of time.

In addition as the present invention does not require the highly innervated and tough structures of the lower abdomen wall or rectus sheath to be punctured, which require considerable force to be

applied by the surgeon, to enable location and fixing of the implant the trauma suffered by the patient is considerably reduced. Due to the decreased trauma suffered by the patient the above procedure may be carried out under local anaesthetic in an outpatient or office setting.

As a greater number of major blood vessels are found located in the retropubic space toward the rectus sheath, suitable placement of the anchor lower in the retropubic space minimises damage to blood vessels, reducing the amount of blood which might be lost by the patient.

Further, as there is not a requirement to anchor the fixing zone of the tape toward the rectus sheath, staying medially the tape can be placed lower and more laterally in the retropubic space toward the endopelvic fascia this reduces the chance of damage to anatomical structures such as the bladder. In view of the decreased risk of damaging the bladder the described procedure may be performed without the need for per operative cystoscopy. This reduces the overall time taken to perform the procedure, further reduces the pain and trauma suffered by the patient and reduces the expense of the procedure.